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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,744	09/10/2003	Akihiko Miyamoto	031145	3385
38834	7590	09/23/2004	EXAMINER	
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/658,744

Applicant(s)

MIYAMOTO, AKIHIKO

Examiner

Andrea M. Ragonese

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed on June 23, 2004 has been entered. Examiner acknowledges that **claim 1** has been amended, **claim 2** has been canceled and **claims 3-11** have been added.

### *Response to Arguments*

2. Applicant's arguments, see pages 11-13, filed June 23, 2004, with respect to the rejection of **claims 1-2** under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference.

### *Drawings*

3. The drawings were received on June 23, 2004. These drawings are acceptable.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-11** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the terms "small opening", "opening", "first opening" and "second opening" renders the claims vague and indefinite for failing to properly set forth the metes and bounds of the claimed invention. When Applicant

refers to an "opening" in the claims, it is unclear exactly to which "opening" is being referred.

6. Any rejections in this Office action have been made by applying any pertinent prior art in the field to the merits of the claimed invention as best understood by the Examiner.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1 and 3-11** are rejected under 35 U.S.C. 102(b) as being anticipated by Sladek (US 6,039,042).

- Regarding **claims 1 and 7**, Sladek discloses a metered dose inhaler **40** with a removable whistle **15** attached to a second opening **42** for air intake provided at a part of a mouthpiece **40A** located on an inhalation passage **31** of a finely powder drug (column, 3, lines 51-67), as shown in Figure 1.
- Regarding **claims 1, 3, 7 and 8**, when installed, the removable whistle **15** makes a sound when the inhalation is properly done (column 4, lines 7-14), as shown in Figure 4, and when removed, the whistle sound is not made at all.
- Regarding **claims 4, 9 and 10**, the inhaler **40** utilizes a first opening **42** for introducing air to take up a finely powdered drug into the delivery passage

**11D.** The Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, Applicant recites, "to correct the difference..." Sladek discloses an inhaler **40** in which the claimed functional limitation can inherently be performed since the inhaler **40** utilizes at least one second opening **17** that is capable of correcting the difference between the lung capacity in the inhalation and the air flow rate in the delivery passage **11D** of the finely powdered drug as to prevent breathing difficulty (column 5, line 22 through column 6, line 10).

- Regarding **claims 5-6 and 11**, the mouthpiece has at least two small openings for air intake, formed between the radial spokes **29**, from or into which the whistle may be removed or placed, as shown in Figure 2A.

9. Applicant is reminded that functional language recitations are statements of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP § 2114. Therefore, as broadly interpreted by the Examiner, the previously presented rejection is applied to **claims 4, 9 and 10** based on the prior art of record. See *In re Swinehart*, 169 USPQ 226 (CCPA 1971); *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

**Conclusion**

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sackner et al. (US 4,484,577) and Kreamer (US 5,758,638) both disclose inhaler utilizing whistles that make a sound to indicate the inhalation was properly done.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **(703) 306-4055**. The examiner can normally be reached on Monday through Friday from 8 am until 4 pm.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR



Henry A. Bennett  
Supervisory Patent Examiner  
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